510(k) Summary

SEP 2 6 2011

Astra Tech AB
Astra Tech Implant System Plus

K111287

September 26, 2011

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Astra Tech AB Aminogatan 1, P.O. Box 14 Mölndal, Sweden SE-431-21 Telephone: +46 31 776 30 00 Fax: +46 31 776 30 10
Official Contact:	Christina Lewing Head of Regulatory Affairs
Representative/Consultant:	Linda K. Schulz, BSDH, RDH Kevin A. Thomas, PhD PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 email: lschulz@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Astra Tech Implant System Plus
Component Name:	OsseoSpeed™ Plus implants and abutments
Common Name:	Dental implant and abutment
Classification Regulations:	Implant, endosseous, root form Endosseous dental implant abutment Class II, 21 CFR 872.3640
Product Code:	DZE, NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

OsseoSpeed™ Plus implants of the Astra Tech Implant System Plus are intended to be used:

- To replace missing teeth in single or multiple unit applications within the mandible or maxilla
- For immediate placement in extraction sites and partially or completely healed alveolar ridge situations
- For both one- and two-stage surgical procedures
- Especially well in soft bone applications where implants with other implant surface treatments may be less effective
- Together with immediate loading protocol in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.

Abutments:
Astra Tech Implant System Plus abutments are intended to be used in conjunction with the Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.

DEVICE DESCRIPTION

OsseoSpeed Plus implants are straight, self-tapping, threaded, root-form dental implants provided in multiple diameters and lengths with the previously cleared OsseoSpeed™ surface. Implants are available in diameters of 3.6 mm, 4.2 mm and 4.8 mm and lengths of 9 mm, 11 mm and 13 mm. The neck portion of the implant includes the MicroThread™ design. A new anti-rotation interface with 6 keyway cross section connections allows for six abutment positions. All other features and procedures of OsseoSpeed Plus implants are the same as presently cleared OsseoSpeed implants.

OsseoSpeed Plus abutment components consist of cover screws, healing abutments and abutments with corresponding screws. Cover screws and healing abutments are provided in sizes to match the implant platform. Healing abutments are provided in sizes to match the implant platform and various gingival diameters and gingival heights. OsseoSpeed Plus abutments have three design types, cylindrical, asymmetric and angled (20°). Each abutment design type is provided in three platform diameters (3.6, 4.2 and 4.8 mm), two prosthetic margin diameters (4.5 and 5.5 mm or 5.5 and 7.0 mm) and two gingival heights (low = 1.5- 2.5 mm and high = 2.5-3.5 mm) for a total of eleven abutment design combinations.

To assist in preoperative treatment planning of position and direction of implant placement, transparent radiographic implant guide sheets are provided with magnifications from 1.0X to 1.8X. The radiographic implant guides are usable with all OsseoSpeed Plus implants.

EQUIVALENCE TO MARKETED DEVICE

Astra Tech AB demonstrated that, for the purposes of FDA's regulation of medical devices, the Astra Tech Implant System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Astra Tech AB, Astra Tech Implant System cleared under K101732,

Astra Tech AB, Astra Tech Implant System cleared under K091239,

Astra Tech Inc., Fixture MicroThread™ OsseoSpeed™ cleared under K053384, and

Altatec GmbH, CAMLOG Implant System Modified Implants and Abutments cleared under K083496.

The subject device and the predicate devices have the same intended use, have the same technological characteristics and are made of the same materials. They encompass the same range of physical dimensions, including diameter and length of the implants, and diameter, height and angle of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. The technological change from the Astra Tech Implant System OsseoSpeed implants is the new anti-rotation feature of keyway cross section connections which is similar to the cam anti-rotation mechanism of the CAMLOG Implant System. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

Performance testing was provided to demonstrate substantial equivalence and included methods described in ISO 14801.

The Astra Tech Implant System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Astra Tech AB
C/O Ms. Linda K. Schulz
Regulatory Affairs
Paxmed International, LLC
11234 Camino Real, Suite 200
San Diego, California 92130

SEP 26 2011

Re: K111287
Trade/Device Name: Astra Tech Implant System Plus
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: DZE, NHA
Product Code: II
Dated: September 13, 2011
Received: September 14, 2011

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

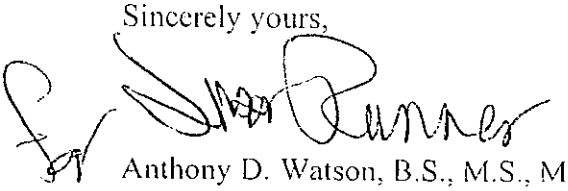
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K111287

Device Name: Astra Tech Implant System Plus

Indications for Use:

Implants:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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